



Doctcket No.: 070119-0015

## DECLARATION

As a below named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter claimed and for which a patent is sought on the invention entitled **T CELL REGULATORY GENES ASSOCIATED WITH IMMUNE DISEASE**, the specification of which

is attached hereto.  
 was filed on September 15, 2003, as United States Application Number 10/663,497, and  
 is a Continuation-In-Part (CIP) of Application Number 10/188,012, filed July 1, 2002.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known to me to be material to patentability in accordance with Title 37, Code of Federal Regulations, Section 1.56 including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35, United States Code, Section 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent or inventor's or plant breeder's right certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's, or plant breeder's rights certificate, or any PCT international application having a filing date before that of the application on which priority is claimed:

**Prior Foreign Applications(s):**

Number	Country	Day/Month/Year filed	Priority Claimed
			<input type="checkbox"/> <input type="checkbox"/>

I hereby claim the benefit under 35 United States Code, Section 119(e) of any United States provisional application(s) listed below.

**Prior Provisional Application(s):**

Application Number	Filing Date
60/302,344	June 29, 2001

Serial No.: 10/663,497

I hereby claim the benefit under 35, United States Code, Section 120 of any United States application(s) or 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35, United States Code, Section 112. I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

**Prior U.S. Application(s):**

Application No.	Filing Date	Status: Patented, Pending, Abandoned
10/188,012	July 1, 2002	Pending

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

---

Full name of sole or first inventor: MCINTIRE, Jennifer Jones

Inventor's signature: *Jennifer Jones McIntire* Date: 12/18/04

---

Residence: Palo Alto, California

---

Citizenship: U.S.A.

---

Post Office Address: 1106 Clark Way

---

Full name of sole or first inventor: DEKRUYFF, Rosemarie

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

---

Residence: Stanford, California

---

Citizenship: U.S.A.

---

Post Office Address: 825 Allardice Way



Serial No.: 10/663,497

I hereby claim the benefit under 35, United States Code, Section 120 of any United States application(s) or 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35, United States Code, Section 112. I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

**Prior U.S. Application(s):**

Application No.	Filing Date	Status: Patented, Pending, Abandoned
10/188,012	July 1, 2002	Pending

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

---

Full name of sole or first inventor: MCINTIRE, Jennifer Jones

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Residence: Palo Alto, California

Citizenship: U.S.A.

Post Office Address: 1106 Clark Way

---

---

Full name of sole or first inventor: DEKRUYFF, Rosemarie

Inventor's signature: Rosemarie DeKruyff Date: 12/13/04

Residence: Stanford, California Newton MA

Citizenship: U.S.A.

Post Office Address: 825 Allardice Way 522 Dudley Rd

---

Serial No.: 10/663,497

---

Full name of sole or first inventor: UMETSU, Dale T.

Inventor's signature: Dale T. Umetsu Date: 12/13/64

Residence: ~~Stanford, California~~ Newton, MA 02459

Citizenship: U.S.A.

Post Office Address: 825 Allardice Way 522 Dudley Road

---

---

Full name of sole or first inventor: FREEMAN, Gordon

Inventor's signature: Date:

Residence: Boston, Massachusetts

Citizenship: U.S.A.

Post Office Address: 44 Binney Street

---

Serial No.: 10/663,497



Full name of sole or first inventor: UMETSU, Dale T.

Inventor's signature:

Date:

Residence: Stanford, California

Citizenship: U.S.A.

Post Office Address: 825 Allardice Way

Full name of sole or first inventor: FREEMAN, Gordon

Inventor's signature: *Gordon Freeman*

Date: 12.2.04

Residence: Boston, Massachusetts

Citizenship: U.S.A.

Post Office Address: 44 Binney Street



Bucket No.: 070119-0015

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : MCINTIRE, Jennifer Jones, et al. Customer No.: 41552  
Appl. No. : 10/663,497 Confirmation No.: 2319  
Filed : September 15, 2003  
Title : T CELL REGULATORY GENES  
ASSOCIATED WITH IMMUNE  
DISEASE  
Grp./A.U. : Not Yet Assigned  
Examiner: : Not Yet Assigned

**SMALL ENTITY STATEMENT**

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

“Business concern” means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The “number of employees” is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months. “Employees” includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are “affiliates” of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

**(3) Nonprofit organization:**

A university or other institution of higher education located in any country. § 1.27(a)(3) (ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B),(D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C),(D).

**Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).**

I hereby assert that I am empowered to sign on behalf of the party identified below (“Party”). Persons empowered to sign include, but are not limited to, an inventor him- or herself or an authorized officer of an assignee or licensee. *See* § 1.27(c)(2).

I have made a determination of the Party’s entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. The other party having rights in the invention is Dana-Farber Cancer Institute and Telos Pharmaceuticals. Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

November 25, 2004  
Date

Name: Katharine Ku  
Title: Director, Technology Licensing

The Board of Trustees of the  
Leland Stanford Junior University  
1705 El Camino Real  
Palo Alto, California 94306-1106



Docket No.: 070119-0015

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : MCINTIRE, Jennifer Jones, et al. Customer No.: 41552  
 Appl. No. : 10/663,497 Confirmation No.: 2319  
 Filed : September 15, 2003  
 Title : T CELL REGULATORY GENES  
         ASSOCIATED WITH IMMUNE  
         DISEASE  
 Grp./A.U. : Not Yet Assigned  
 Examiner: : Not Yet Assigned

SMALL ENTITY STATEMENT

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

“Business concern” means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The “number of employees” is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months. “Employees” includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Serial No.: 10/663,497

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

**(3) Nonprofit organization:**

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B),(D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C),(D).

**Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).**

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include, but are not limited to, an inventor him- or herself or an authorized officer of an assignee or licensee. *See* § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. The other party having rights in the invention is The Board of Trustees of the Leland Stanford Junior University and Telos Pharmaceuticals. Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

Serial No.: 10/663,497

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

December 2, 2004  
Date

Name: Patricia J. Balle  
Title: PATENT COUNSEL

Dana-Farber Cancer Institute, INC.  
75 Francis Street 44 BINNEY ST  
Boston, Massachusetts 02115

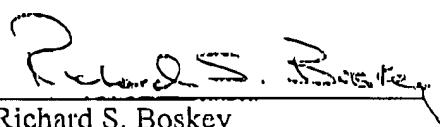


Dana-Farber Cancer Institute, Inc.  
Certificate of Corporate Authority

I, Richard S. Boskey, Assistant Secretary of Dana-Farber Cancer Institute, Inc., a Massachusetts not-for-profit corporation with its usual place of business at 44 Binney Street in Boston, Massachusetts (the "Corporation"), hereby certify that Pamela D. Ariniello, acting in her capacity as Patent Counsel of the Corporation, is authorized to act on behalf of and bind the Corporation as to the matters specified below:

Copyright, Patent and Trademark Applications and Related Documents

Executed this 23<sup>rd</sup> day of September, 2003.

  
\_\_\_\_\_  
Richard S. Boskey  
Assistant Secretary  
Dana-Farber Cancer Institute, Inc.